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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,222	01/17/2007	Craig Hardy	W004 P01438-US	8399
3017 7590 11/24/2008 BARLOW, JOSEPHS & HOLMES, LTD. 101 DYER STREET 5TH FLOOR PROVIDENCE, RI 02903			EXAMINER SUTTON, DARRYL C	
			ART UNIT 1612	PAPER NUMBER
			MAIL DATE 11/24/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/578,222	Applicant(s) HARDY, CRAIG	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☒ Claim(s) 5, 6, 10, 11, 11, 16 and 23 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>05/03/2006</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claims 5, 6, 10, 11, 11, 16 and 23 are objected to because of the following informalities: The word “aid” in line 1 of claim 5 should read “said”. The word “stabilisers” in line 3 of claim 16, the word “pyrolodine” in line 3 of claim 7 and the word “sensitise” in line 2 of claim 23 are misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1) Claims 7, 12, 13, 14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “polyacrylic acid based” in line 3 of claim 7, renders the claim indefinite.

The term “peroxide based” in line 2 of claim 13, render claims 13 and 14 indefinite.

The term "silicone based" in line 2 of claim 17, renders the claim indefinite.

There is no way to ascertain how closely related a compound must be to polyacrylic acid, peroxide and silicone to be considered a “polyacrylic acid based” polymer, a “peroxide based” whitening agent and a "silicone based" compound.

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Claim 12 contains the trademark/trade name Pluronic®. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe block copolymers based on ethylene oxide and propylene oxide and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 101/35 USC § 112 – Use Claims

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 19 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 19 provides for the use of a tooth-whitening composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 13-16, 19, 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sintov (U.S. 5,425,953).

Sintov teaches a solution for bleaching teeth or prevention of tooth discoloration, treating dental plaque and gingivitis comprised of a bleaching agent/oxidizing agent and a water soluble cellulosic polymer (Abstract, column 1, lines 7-17, and column 6, lines

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64-68). The film forming composition adheres to the dentin layer of teeth and forms a film which disintegrates in relatively short periods of time, but not before the release of the bleaching agent is complete (column 3, lines 1-8 and lines 23-26, column 4, lines 40-45). The composition optionally contains a stabilizing additive (column 4, lines 37-39). Example 1, is a composition comprised of a carbamide peroxide, a bleaching/oxidizing agent; tetrasodium edetate, a stabilizer; and hydroxypropyl cellulose, a cellulosic polymer (column 10, lines 40-45). The composition of the invention is useful for antiplaque treatment, for gingivitis treatment and for treatment of other oral or periodontal diseases in the same doses and application as for tooth bleaching (column 6, lines 7-14). The oxidizing agent is preferably a peroxide compound including hydrogen peroxide and carbamide peroxide, i.e. urea peroxide, in amounts from about 1 to about 15% by weight (column 7, lines 47-51). The cellulosic polymer is present in the composition in amounts ranging from about 5 to about 15% by weight. The compositions were cast on teflon plates to prepare films (column 11, lines 1-5).

The prior art anticipates the instant claims insofar as it discloses a tooth-whitening composition comprised of carbamide peroxide whitening agent, a stabilizer and a cellulosic polymer which forms a film and self adheres to teeth; the composition is cast into the form of a film. Since the composition of the reference is comprised of substantially the same components in substantially the same amounts as the composition of the instant claims, if it were used to whiten teeth it would inherently dissolve upon contact with water over a time ranging from about 15 seconds to up to

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about 120 minutes; self adhere to teeth in a time period of from about 0.5 seconds to 2 minutes; and not desensitize teeth.

2) Claims 1-15, 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Prosise et al. (U.S. 2004/0086468).

Prosise et al. teach a delivery system for delivering a tooth whitening substance to the surface of the oral cavity comprising a film having a tooth whitening substance as an integral part of said film. When said film is adhered to the oral surface, said film has a dissolution rate such that the whitening substance can release its active, and said film is disintegrable thereafter affecting the tooth whitening action (Abstract, paragraph [0007]). The active is hydrogen peroxide complexed with PVP polymer [0009]. The delivery system comprises a film made of PVP-H₂O₂ and ethylcellulose, hydroxypropylmethyl cellulose and glycerol [0011], [0016]-[0018]. The solution of 3.2 g PVP and 0.8 g H₂O₂, i.e. PVP- H₂O₂ complex that is 20% H₂O₂, 3 g glycerol, 4.2 g hydroxypropylmethyl cellulose, 2.8 g of ethylcellulose, and 78.9 g ethanol, i.e. 100 mL of ethanol with density of .789 g/mL, is mixed and poured on a film forming apparatus, the ethanol is gently dried away to produce a film containing 2-6% hydrogen peroxide [0017], i.e. the composition is cast into a film comprised of 22.5% plasticizer, 31.5% cellulosic polymer, base on a film with 6% hydrogen peroxide content.

The prior art anticipates the instant claims insofar as it discloses a tooth whitening film comprised of hydrogen peroxide tooth whitening agent together with a

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cellulosic polymer, glycerol plasticizer, and ethyl cellulose filler. Since the composition of the prior art is comprised of substantially the same components in substantially the same amounts as the composition of the instant claims, if it were used to whiten teeth it would inherently dissolve upon contact with water over a time ranging from about 15 seconds to up to about 120 minutes; self adhere to teeth in a time period of from about 0.5 seconds to 2 minutes; and not desensitize teeth.

Claims 1-16 and 18-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Moro et al. (U.S. 2004/0062724).

Moro et al. teach an erodible film that adheres to teeth and delivers an active compound before eroding at a predetermined rate (Abstract, [0002]). The first layer comprises a tooth-whitening agent, hydrogen peroxide, and at least one water-soluble film forming polymer in combination with at least one mucoadhesive polymer; the second layer is a pre-made film comprised of a combination of hydroxypropylmethyl cellulose and other cellulosic polymers, including ethyl cellulose, PVP or polyvinyl alcohol [0009]. The first layer, i.e. polymeric coating layer, is comprised of one or more adhesive polymers, an appropriate whitening agent and a plasticizer [0013]. The adhesive polymers include cellulosic polymers, PVP, polyacrylic acid, or combinations thereof [0014]. The whitening agent, include peroxides in amounts from about 0.1 to about 30% by weight [0016]. The device may be used for the delivery of fluoride ions and phosphates [0010]. Plasticizers are used in the composition including polyhydric alcohols such as glycerin in amounts from about 0.2 to about 30% by weight [0018]. A

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colorant can be incorporated in the adhesive layer [0020]. Example 2 teaches a composition of the invention comprised of a hydroxylethyl cellulose polymer, propylene glycol plasticizer and carbamide peroxide whitening agent [0035]. Once dissolved, the solutions of the adhesive and backing are cast and processed into a thin film by techniques known in the art such as film dipping, spray drying [0024]. The casting surface may be a precast or freshly cast adhesive on a backing layer.

Moro et al. anticipate the instant claims insofar as it discloses a composition comprised of a cellulosic polymer, carbamide peroxide tooth-whitening agent, and a plasticizer, which is cast into a film that adheres to the teeth and subsequently erodes thereby whitening teeth; alternately the composition can be processed into a film by application onto a precast film through film dipping or spraying. Since the composition of the prior art is comprised of substantially the same components in substantially the same amounts as the compositions of the instant claims, if it were used to whiten teeth it would inherently dissolve upon contact with water over a time ranging from about 15 seconds to up to about 120 minutes; self adhere to teeth in a time period of from about 0.5 seconds to 2 minutes; and not desensitize teeth.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1) Claim 17 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sintov as applied to claims 1-5, 13-16, 19, 20 and 23 above, and further in view of Dana (U.S. 2003/0003059).

Sintov is discussed above.

Sintov does not teach that the composition is comprised of a silicone based compound or that the composition does not sensitize teeth.

Dana teaches an oral care composition which is useful for whitening teeth (Abstract). Dana teaches that the composition can be in the form of a film [0036]. Cellulosic polymers are included in amounts from about 0.05-about 25% [0042]. Whitening agents, such as peroxide, are present in the whitening compositions of the instant invention [0052]. The compositions may also comprise components to treat sensitive teeth [0052]. Dimethicone is a film forming agent that also serves to protect the teeth against tar from tobacco and other tannins in amounts between 0.05 and 5% by weight [0063] i.e. a stain protector/preventer.

Dana does not teach a film that is water insoluble.

It is prima facie obvious to select a compound based on its suitability to for its intended use. See MPEP 2144.07. Therefore, it would have been obvious to modify the tooth whitening composition of Sintov to include the dimethicone of Dana as a stain preventer.

In regards to claim 23, the compositions of the combined prior art are comprised of the same components as those of the instant application and therefore would be reasonably expected to function in the same way, i.e. not sensitize teeth.

2) Claims 1-16 and 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moro et al. (WO 03/015748).

Moro et al. teach a layered film for the administration of pharmaceuticals or other actives to mucosal surfaces, comprised of a water soluble adhesive layer, and a bioerodible backing layer (Abstract). The adhesive film layer is water soluble and is comprised of cellulosic polymers, PVP, polymers of polyacrylic acid, sodium alginate or combinations thereof [11] and [20]. The backing layer is a precast film comprised of cellulosic polymers and may include plasticizers [11]. Glycerin is known in the art to be a plasticizer in water soluble films [06]. The invention is most applicable to the treatment of body tissues or wounds that have moist surfaces and that are susceptible to bodily fluids, such as the mouth. Pharmaceuticals are delivered to the treatment site, surrounding tissues for a prolonged period of time [14]. The active ingredients may be incorporated in the adhesive layer, backing layer or both. Flavorants, penetration enhancers, and stabilizers may be added to the layer or layers containing the active ingredients in amounts of up to 5% by weight [28] and [48]. Pharmaceuticals include anesthetics, bactericides and disinfectants in amounts from 0.001 to 30% by weight [29] and [36]. It is known in the art that hydrogen peroxide has wide utility as an antiseptic, i.e. a disinfectant, and antibacterial the oral cavity.¹ The layers are cast and processed into films by techniques known in the art, such as film dipping, film coating, or spray

¹ Merianos, U.S. 5,130,124, column 1, lines 14-38.

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drying [51]. In another embodiment the solutions are both cast into films then laminated together using roller under pressure [52].

Moro et al. do not teach a film comprised of hydrogen peroxide or a film used to whiten teeth. Moro et al. do not teach an embodiment with stabilizers in the adhesive film layer.

In regards to claims 1-5 and 13-15, it is prima facie obvious to select a compound based on its suitability for its intended purpose. Therefore, it would have been obvious to modify the composition of the adhesive film layer of Moro et al. to include hydrogen peroxide as a disinfectant and bactericide, since it is known in the art that hydrogen peroxide has wide utility as an antiseptic, i.e. a disinfectant, and antibacterial in the oral cavity.²

In regards to claim 16, it would have been obvious to include a stabilizer in the adhesive film layer since Moro et al. teach that stabilizers can be incorporated into the adhesive layer, backing layer or both.

In regards to claim 10, it is prima facie obvious to select a compound based on its suitability for its intended purpose. Therefore, it would have been obvious modify the composition of Moro et al. to include glycerin as the plasticizer.

In regards to claims 19, it would have been obvious to use the modified invention of Moro et al. to whiten teeth since Moro et al. teach the film can be use in the mouth and that not only is mucosal tissue treated, but active ingredients are delivered to

² Merianos, U.S. 5,130,124, column 1, lines 14-38.

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surrounding tissue, i.e. teeth, and the active ingredient, hydrogen peroxide, in the composition will function to whiten teeth.

In regards to claims 6-9 and 11 it would have been obvious to modify the composition of the backing film layer to be comprised of an active agent, i.e. a disinfectant, hydrogen peroxide, a cellulosic polymer and a stabilizer, since Moro et al. teach that the backing film layer is comprised of a cellulosic polymer and a stabilizer, and that the active ingredient can be incorporated into either the backing film or adhesive film layer; and it is known in the art that hydrogen peroxide is a disinfectant and a bactericide.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612